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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/424,482	02/29/2000	YEN CHOO	PM264974	8038

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EXAMINER

WESSENDORF, TERESA D

ART UNIT PAPER NUMBER

1639

DATE MAILED: 12/20/2002

Restart

Please find below and/or attached an Office communication concerning this application or proceeding.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/787,182	05/29/2001	Masatoshi Ito	1083	6537

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11/07/2002

Schnader Harrison Segal & Lewis
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1600 Market Street
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EXAMINER

ROSE, SHEP K

ART UNIT

PAPER NUMBER

1614

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Please find below and/or attached an Office communication concerning this application or proceeding.

Restart 12-20-02 due to wrong cover
sheet went out on the action.

12-20-02
B. Gray

Office Action Summary

Application No.

09/424,482

Applicant(s)

CHOO ET AL.

Examiner

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,8 and 10-25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,6,7 and 9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 29.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 26. 6) ☐ Other:

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DETAILED ACTION

Election/Restrictions

As a preliminary matter, applicants state that claims 1-7 were amended in the PCT phase in a letter dated May 12, 1999. However, there is no copy on the record of said amendment.

Applicant's election with traverse of Group I claims 1-3, 6-8 and 9-18 in Paper No. 28 is acknowledged. The traversal is on the ground(s) that the rule states that unity of invention is fulfilled when there is a special technical relationship among those inventions involving one or more of the same or corresponding special technical features. The unity of invention is satisfied between two groups of claims if the groups have a special technical feature in common. It is further argued that the rule does not require that two groups of claims have every technical feature in common. All of the present claims incorporate the special technical feature of randomization extending to cover the overlap of a single pair of zinc fingers. Here, claim 1 of Group I recites the special technical feature that randomization extends to cover the overlap of a single pair of zinc fingers. Claim 4 of Group II depends from claim 1 include the same technical feature, so are claim 19 of Group III and claim 23 of Group IV (both dependent on claim 1). Because all of the claims share a special technical feature, there is a

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unity of invention. This is not found persuasive because MPEP 1893.03(d) defines the expression special technical features as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art. Thus, each of the claims in each Groups considered as a whole, does not form a unity of invention. Based on the prior art and applicants' disclosure, Group I, drawn to a randomized peptide that cover the overlap of a single pair of zinc fingers, does not render obvious Group III, method of preparing a library of Cys2-His2 zinc finger class. The library of DNA binding protein can be made by different methods such as by prokaryotic, bacteriophage, in vitro utilizing different cells, expression vectors and/or primers. Furthermore, the library of Group I can be used as therapeutic agents as stated at pages 29-30, rather, than Group IV method of using the library to determine the presence of a target nucleic acid molecule. Accordingly, in view of the prior art, the different inventions of Groups I-IV are distinct and different, so taken as a whole, each of the Groups contains additional features. A prior art reference anticipating e.g., Group I would not render obvious the other Groups of the claimed inventions.

The requirement is still deemed proper and is therefore made FINAL.

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Applicants' election of species A is noted. It is further noted that the claims without any linker is the elected species. The species restriction in subgroup A is clearly intended to be without any linker. This is evident from the claims recited therein i.e., claim 9, without a linker. Group B is with a linker, as stated in the Office action, as recited in claim 15. Accordingly, species A is without a linker, and applicants' election of this species is acknowledged.

Claims 4-5, 8 and 10-25 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species with linker, there being no allowable generic or linking claim. Applicants timely traversed the restriction (election) requirement in Paper No. 28.

Status of Claims

Claims 1-3, 6-7 and 9 are pending in the application.

Claims 4-5, 8, 10-25 are withdrawn from consideration.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The specification has not been checked to the extent necessary to determine the presence of all possible minor

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errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 6-7 and 9 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

The claimed library of zinc finger polypeptide with random amino acids that extends to cover the overlap of a single pair of zinc fingers lacks patentable utility. The claimed library are nothing more than a collection of starting materials, that can be compared to products that are found in nature, that needs to be screened to isolate and identify a purified product with a function. The specification at e.g., pages 29-30 provide too numerous general, theoretical statements as to how a compound can be made into a pharmaceutical composition and other uses. A library is not a compound. Rather, a mixture or collection of different compounds from which ultimately a compound with perhaps, a pharmacological property can be isolated, purified and identified. Therefore, it is not apparent from the disclosure, if the compound(s) being referred to is the claimed library. This is made more perplexing since there is not a

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single use illustrated for the compound(s) in the Examples. All of the examples provided in the disclosure describe a method of making the library. No intended use is exemplified or demonstrated in any of the given Examples. One skilled in the art would have not deemed the general statement in the specification that a library comprising of different mutated DNA binding zinc finger protein would be useful as a therapeutic agent or as a component of a ready to use pharmaceutical composition. 35 USC 101 is clear in its requirement that a patent is granted for a **useful product**. Until some actual and specific significance can be attributed to the library or even the compounds, isolated and identified from the library, an artisan would be required to perform additional experimentation in order to determine the use of the claimed library. "Congress intended that no patent be granted on a chemical compound whose sole 'utility' consists of its potential role as an object of use-testing." *Brenner*, 148 USPQ at 696. Further, In *Brenner*, the Court approved a rejection for failure to disclose any utility for a compound where the compound was undergoing screening for possible compounds the utility of which has also not been identified. *Brenner*, 148 USPQ at 690. A collection of compounds i.e., a library is nothing more than starting material or raw products from which a useful product can be isolated and purified that exhibits a specific utility.

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Claims 1-3, 6-7 and 9 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a practical asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention as a therapeutic agent or as a pharmaceutical or even diagnosis. It is not apparent as to the type of diseases, if any, can be diagnosed by the claimed library.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 6-7 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). The language "at least partially randomized such that the randomization extends to cover the overlap of a single pair of zinc fingers" is indefinite, as the language relates more to a process rather than a definite description of the library. (Claim 1). It is suggested that applicants recite which position of the zinc finger is a random residue. Furthermore, it is not

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clear whether the whole zinc finger peptide is partially randomized as the metes and bounds of the "at least" partial randomization is unclear as to the part of the whole zinc finger peptide is randomized. It is not clear, within the claimed context, a "single pair" of zinc fingers.

B). Claim 3 is indefinite as to the randomized polypeptide being one and a half zinc fingers, especially since the zinc fingers are not clearly characterized, in the context of the claim.

C). "The randomized positions" in claim 6 lack antecedent basis of support from the base claim. The base claim does not recite for any positions, let alone, the numbered positions. This rejection also applies to claim 7. The term "may" and "possible" fails to ascertain the claimed invention with precision. It is not clear whether the different amino acids are clearly present in each of the recited positions. Claim 7 is further unclear as to the restriction imposed on the random residues such that the different recited residues at the specified positions are contained therein.

D). Claim 9 broadens the base claim 1 in its recitation of the different provisos. Claim 1 relates to polypeptide, not nucleotides. "If" provides for uncertainty and ambiguity.

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3, 6-7 and 9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of U.S. Patent No.

6,007,988 ('988 patent) (Choo et al) in view of Ogata (PNAS, 1992) and Hall et al (Cell Growth and Differentiation).

The '988 patent claims a library of DNA sequences, each sequence encoding a zinc finger polypeptide for display, the zinc finger polypeptide comprising at least one zinc finger having partially randomised allocation of amino acids, the partially randomised zinc finger having a random allocation of amino acids at positions -1, +2, +3 and +6 and at least one of positions +1, +5 or +8, position +1 being the first amino acid

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in the .alpha.-helix of the zinc finger except the '988 Patent does not recite a library of overlapping partially random residues. However, Ogata discloses a tandem repeat of c-myb is essential for sequence specific DNA binding (page 6428, abstract and page 6431, last paragraph). Hall discloses at page 207 that all members of nuclear hormone receptor family (which will include the oncogene myb of Ogata) share a common modular structure consisting of a cys rich Zinc finger domain that confers DNA binding. Accordingly, it would have been obvious to one having ordinary skill in the art at the time the invention was made to make the library of Choo with an overlapping residues since Ogata discloses that an overlapping or tandem repeats is essential for sequence specific DNA binding. One would be motivated to have an overlapping repeats to obtain a diverse compounds from a library with such sequence binding specificity thus, resulting in compounds with more or increased pharmacological effects or potency due to the high specificity action or binding.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 6-7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choo et al (Current Opinion in Biotechnology) in view of Ogata (PNAS, 1992) and Hall et al (Cell Growth and Differentiation).

The Choo et al reference published in the Current Opinion in Biotechnology presents the same disclosure as the Choo ('988 Patent). The rejection under the obviousness double patenting above, applies herein.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Loeb et al discloses a sequence of L1MD with tandem repeats.

REASSIGNMENT OF LOCATION

The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1639.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D.

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Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

T. D. W
T. D. Wessendorf
Primary Examiner
Art Unit 1639

tdw
November 4, 2002